

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION**

MARK WILLIAMS and CAROL WILLIAMS,

Plaintiffs,

v.

ELI LILLY AND COMPANY, an Indiana corporation,

Defendant.

No. 5:14-cv-00460-FL

**PLAINTIFFS' MEMORANDUM IN
SUPPORT OF THEIR MOTION TO
COMPEL**

I. INTRODUCTION

Plaintiffs Mark and Carol Williams respectfully request that the Court compel Defendant Eli Lilly and Company (“Lilly”) to conduct electronic searches and produce the resulting discoverable documents pertaining to the custodial files of six Lilly employees -- sales representatives William Booth, Gay Bolenbaugh, Kevin De Bruhl, John Burke, Tracy Gaskins, and James Kiger -- who communicated with two of Plaintiff Mark Williams’s (“Plaintiff”) treating doctors, Dr. Shehzad Niazi and Dr. Jenny Smith,¹ about Lilly’s prescription drug Cymbalta.

Plaintiffs allege that Lilly did not adequately warn patients or their doctors that stopping Cymbalta treatment could cause severe withdrawal symptoms, and did not provide patients or their doctors with guidance on how to safely stop taking Cymbalta. The six Lilly sales representatives at issue visited Dr. Niazi and Dr. Smith a combined total of 438 times to promote Cymbalta.² Accordingly, the information in these Lilly sales representatives’ custodial files is likely to be highly relevant to Plaintiffs’ claim that Lilly misrepresented the risk of withdrawal symptoms to Plaintiff’s doctors.

¹ Lilly noticed the deposition of *fourteen* of Plaintiff’s doctors in this case. After Plaintiffs objected to Lilly noticing more than ten depositions without obtaining a stipulation from them or leave of court as required by Federal Rule of Civil Procedure 30, Lilly withdrew its deposition notices for six doctors, including Dr. Niazi. However, Lilly has reserved its right to re-notice the withdrawn depositions.

² Sales representatives Bolenbaugh and Burke visited Dr. Niazi a combined total of 94 times over a four-year period. Sales representatives Booth, De Bruhl, Gaskins, and Kiger visited Dr. Smith a combined total of 344 times to promote Cymbalta over a nine-year period, including during her treatment of Plaintiff.

Plaintiffs contend that these six files likely contain relevant documents, and that Lilly's burden to produce them is minimal. Lilly, however, has refused to review, let alone produce, them. Because Lilly has refused to even review these six sales representatives' files, it has not produced any data to allow Plaintiffs to assess Lilly's claim of undue burden. Plaintiffs therefore seek an order compelling Lilly to produce the discoverable documents contained in the custodial files of these six sales representatives and to do so without first using unnecessary and improper date restrictions during its searches of those files.

II. BACKGROUND

A. Plaintiffs Requested Lilly's Sales Representatives' Files And The Promotional Materials Shown To Plaintiff Mark Williams's Doctors More Than A Year Ago.

More than one year ago, Plaintiffs served Lilly with their First Set of Requests for Production ("RFP"). Plaintiffs requested production of the complete custodial file of each pharmaceutical representative who promoted Cymbalta to Plaintiff's doctors, and separately requested production of documents shown or given to Plaintiff's doctors. Declaration of Khesraw Karmand ("Karmand Decl."), Ex. A at 28-29 (RFP No. 91), 32-33 (RFP No. 95). Lilly objected that the requests were overboard and unduly burdensome, and with respect to the request for documents shown or given to Plaintiff's doctors, Lilly responded that "the information in its sales database does not indicate which marketing materials or other documents were shown to particular medical professionals." Ex. C at 63-64 (Response to RFP No. 91), 68-69 (Response to RFP No. 95). Lilly did, however, agree to produce, in response to a different request for production, "documents tracking sales calls to [Plaintiff's doctors] that can be located through a reasonably diligent search, to the extent any such documents or sales calls exist." *Id.* at 65-66 (Response to RFP No. 92).

B. Plaintiffs Narrowed Their Request Based On The Limited Information Provided By Lilly And Lilly's Complaint Of Undue Burden.

Five months after it responded to Plaintiffs' RFPs Lilly finally produced its' sales call tracking spreadsheets, which identified thirty-five Lilly sales representatives who visited five of Plaintiff's treating doctors a combined total of 1,046 times to promote Cymbalta. Based on Lilly's objections to Plaintiffs' RFPs, and the information on the sales representatives' calls on Plaintiff's doctors set forth in the sales call

tracking spreadsheets, Plaintiffs narrowed their request to the files of only nine sales representatives who called on Plaintiff's doctors a combined total of 577 times. Ex. D. Plaintiffs' narrowed request sought only the files of sales representatives who visited Plaintiff's doctors before or during the doctors' treatment of him for Cymbalta withdrawal symptoms. *Id.*

In response, Lilly insisted that Plaintiffs agree to a narrow set of search terms to use in its search for discoverable documents, which Lilly proposed without having reviewed a single sales representative file or having run the proposed search terms across any documents to determine whether the search terms would not exclude relevant documents. Ex. E.

That same week, Plaintiffs' counsel (Kash Karmand) and Lilly's counsel (Brett Reynolds) conferred via telephone. During the telephonic conferences, Plaintiffs asked Lilly to provide data to permit them to assess Lilly's claim of undue burden; **Lilly responded that no such data was available because Lilly had not reviewed any sales representatives' files.** Karmand Decl., ¶ 3. Plaintiffs also asked that Lilly allow them to sample the files of one or two sales representatives to ensure that Lilly's proposed search terms were adequate, a request that Lilly rejected. *Id.*

In November, the parties agreed to resume their negotiations based on a broader set of search terms agreed to by Lilly and plaintiffs in a related Cymbalta lawsuit. The parties conferred via telephone and agreed that they would use a broader set of search terms which Plaintiff would send to Lilly sometime in December. The parties also agreed that Lilly would turn to the sales representative files in this case after it completed its production of the sales representative files in several other Cymbalta cases. *Id.*, ¶ 4.

In early January 2016, Plaintiffs sent Lilly a proposed list of search terms and asked Lilly to run the search terms across the files of the nine sales representatives identified in their letter of September 23, 2015. *See* Ex. F at 14; Ex. G (list of search terms). Lilly responded by insisting, pertinent to the present dispute, that Plaintiffs limit their request to the files of no more than five sales representatives who promoted Cymbalta to Plaintiff's prescribing doctor or any doctors who oversaw his discontinuation of Cymbalta. Ex. F at 13. **Again, Lilly provided no data to support its insistence that Plaintiffs limit their request to the files of five sales representatives.**

C. Plaintiffs Further Narrowed Their Request Despite Lilly's Continued Refusal To Provide Data Concerning Its Burden.

Plaintiffs responded that they had not agreed to an arbitrary limit of five custodial files and that their request was already narrowly tailored because they were only requesting the files of nine sales representatives out of the thirty-five identified in Lilly's sales call tracking spreadsheets. Ex. F at 11-13. Nonetheless, in a good-faith effort to reach a compromise, Plaintiffs revised their request, reducing the list from the files of nine sales representatives to the files of eight sales representatives who called on three of Plaintiff's treating doctors (Dr. Paul Bondy, Dr. Niazi, and Dr. Smith) and narrowing the date ranges for each sales representative. *Id.* Lilly then argued that the files of the sales representatives who called on Plaintiff's treating doctors (rather than his prescribing doctor) were not relevant to the litigation. *Id.* at 10-11. This argument was nothing more than speculation, as Lilly had still not reviewed any of those files.

In response, Plaintiffs explained that the files of the sales representatives who called on Plaintiff's treating doctors were indisputably relevant to the issue of causation. *Id.* 7-9. Plaintiffs offered to withdraw their request if Lilly would stipulate that Plaintiff's symptoms were caused by Cymbalta withdrawal. *Id.* at 9. Additionally, Plaintiffs offered to withdraw their request for the files of the two sales representatives who visited Dr. Bondy. *Id.*

At this point, it became apparent that the parties had reached an impasse and would need to seek the assistance of the Court. *Id.* at 6. Plaintiffs thus notified Lilly that they would file a motion to compel the production of the files of the six sales representatives who visited Dr. Niazi and Dr. Smith. *Id.* at 5-6. The parties subsequently clarified the scope of the dispute and agreed to seek the Court's assistance. *Id.* at 3-4.

D. Plaintiffs' Counsel Subsequently Discovered That The Imposition Of Date Restrictions Had Caused Responsive And Relevant Documents To Be Excluded From The Productions Of Sales Representative Files In Other Cymbalta Cases.

Shortly thereafter, while reviewing sales representative files produced by Lilly in a related Cymbalta lawsuit on February 19, 2016, Plaintiffs' counsel became aware that the date restrictions used by Lilly in searching its sales representative files in another Cymbalta case were causing responsive and highly relevant documents to be excluded. After investigating the issue, Plaintiffs' counsel notified Lilly of their

concerns and requested that Lilly not impose date restrictions during its searches of the files. Ex. H. Lilly, however, is unwilling to consider searching the files without date restrictions despite clear evidence that they were causing responsive and highly relevant documents to be excluded. Ex. F. at 1.

Following the Court's text order of March 4 instructing the parties to further confer to narrow the scope of their dispute, Plaintiffs made another good-faith offer of compromise to avoid the need for this motion, offering to withdraw their request for the six sales representatives' files in exchange for the files of three district managers who supervised several Lilly sales representatives who called on Plaintiff's doctors. *Id.* at 2-3. Lilly rejected Plaintiffs' offer on the same grounds (relevance) that it refuses to produce the sales representatives' files. *Id.* at 1.

III. LEGAL STANDARD

Federal Rule of Civil Procedure 26(b) permits litigants to obtain discovery regarding "any nonprivileged matter that is relevant to any party's claim or defense[.]" Fed. R. Civ. P. 26(b)(1). "While Rule 26 does not define what is deemed relevant for purposes of the rule, relevance has been broadly construed to encompass *any possibility* that the information sought may be relevant to the claim or defense of a party." *Martin v. Bimbo Foods Bakeries Distribution, LLC*, No. 5:14-CV-17-BR, 2016 WL 676377, at *3 (E.D.N.C. Feb. 18, 2016) (internal quotations omitted) (emphasis added).

IV. ARGUMENT

A. The Court Should Compel Lilly To Produce The Custodial Files At Issue.

1. The discovery sought is necessary and relevant to the parties' claims and defenses.

Contrary to Lilly's assertion that these files are not relevant (which is based on speculation, as it has not yet reviewed any of the documents in the files), Lilly's communications with Plaintiff's treating doctors are highly relevant to Plaintiffs' claims and Lilly's defenses for multiple reasons.

First, in its defense to similar claims in other Cymbalta withdrawal cases, Lilly has emphasized plaintiffs' doctors' knowledge of Cymbalta. *See, e.g., Hexum v. Eli Lilly & Co.*, No. 2:13-CV-02701, 2015 WL 4064633, at *13-15 (C.D. Cal. June 19, 2015) (in order denying Lilly's motion for summary judgment, discussing proximate cause and Lilly's evidence of prescribing doctor's knowledge of Cymbalta's risks).

Courts and juries deciding other Cymbalta withdrawal cases have focused on whether plaintiffs sought treatment for their withdrawal symptoms and whether plaintiffs were diagnosed with Cymbalta withdrawal. Moreover, Lilly itself has relied on the notes and records of doctors who had treated plaintiffs a single time or after plaintiffs discontinued Cymbalta to oppose plaintiffs' proof of causation. Importantly, Lilly's expert reports in these other, related cases focused on the treating doctors' general knowledge about withdrawal from medications such as Cymbalta. Indeed, Lilly spent significant time at trial questioning the treating doctors about their knowledge of Cymbalta withdrawal. Thus, what Lilly's representatives communicated to Dr. Niazi and Dr. Smith, from whom Plaintiff sought treatment for his withdrawal symptoms, is undeniably relevant to a critical aspect of Lilly's defense.

Second, the doctors' records themselves point to their relevance to the critical question of specific causation. For example, Dr. Niazi's records indicate that following his visit with Plaintiff, he continued to research the etiology of Plaintiff's symptoms; specifically, in an email to his colleague who was overseeing Plaintiff's treatment for withdrawal symptoms at the Mayo Clinic, Dr. Niazi states that he "ha[s] been trying to figure out if there was anything that [he] could find that may help explain why [Plaintiff] had such a response to discontinuation of [Cymbalta] in the recent past." *See* WilliamsM_MC_0069. Thus, Plaintiffs are entitled to discovery of the files of the sales representatives who called on Dr. Niazi, as well as Dr. Smith (whom Plaintiff started seeing pursuant to Dr. Niazi's recommendation) to learn what Lilly communicated (or failed to communicate) to them about the risks of Cymbalta withdrawal and how their opinions and treatment of Plaintiff would have changed had Lilly provided them with complete and accurate information about the risks of Cymbalta withdrawal.

Third, the agreed-upon search terms themselves restrict the documents to those with a high probability of relevance to this case. As explained below in section B. 2, the search terms require that the documents be responsive to both "Cymbalta" **and** the "Discontinuation Terms." *See* Ex. G (list of search terms). Thus, only those documents pertaining to Cymbalta withdrawal, the central issue in this case, will be returned as "hits" to the search terms.

Last, Lilly's primary means of communication with Plaintiff's doctors is through its sales representatives. These six sales representatives visited Dr. Niazi and Dr. Smith 438 times to promote Cymbalta. Considering that Plaintiffs' claims focus on what Lilly both did and did not tell patients and their doctors, that Lilly's anticipated defenses focus on the treating doctors' knowledge of Cymbalta and its risks, that Dr. Niazi and Dr. Smith treated Plaintiff for withdrawal symptoms, that Dr. Niazi searched for information on Cymbalta withdrawal, that Lilly intends to depose Dr. Smith and has reserved its right to depose Dr. Niazi, and that courts and juries have considered Plaintiff's treatment and diagnosis of Cymbalta withdrawal, discovery related to these six sales representatives' 438 direct communications with Dr. Niazi and Dr. Smith falls solidly under the broad scope of discovery contemplated by Rule 26 and is highly relevant to the parties' claims and defenses.

2. Lilly has not demonstrated undue burden.

It is Lilly's burden to demonstrate that the production Plaintiffs request is unduly burdensome. *See Martin*, 2016 WL 676377, at *3 ("The party resisting discovery bears the burden of establishing the legitimacy of its objections."). Here, however, Lilly has continuously refused to provide data to permit Plaintiffs to assess its claim of undue burden, such as the volume of documents returned as "hits" to the agreed-upon list of search terms, and it appears that Lilly has not even looked at the files it refuses to produce. An unsupported assertion of undue burden is insufficient to relieve Lilly of its discovery obligations under the Federal Rules.

Despite Lilly's refusal to provide specific information regarding its supposed burden, in a good-faith effort to resolve the dispute, Plaintiffs narrowed their request and made multiple offers of compromise—reducing their initial request for the custodial files of nine of the thirty-five sales representatives identified in Lilly's sales call tracking spreadsheets to only the files of eight sales representatives, and then further reducing their request to the files of only six sales representatives. Additionally, Plaintiffs offered to withdraw their request for these six sales representatives' files in exchange for the files of three supervising district managers. **In each instance, Lilly has refused Plaintiffs'**

offer of compromise without any data to support its claim of burden, or any legitimate arguments concerning the relevance of these files.

Earlier in the meet and confer process, during the telephonic conferences in October 2015, Lilly claimed that Plaintiffs' request was unduly burdensome because it required Lilly to review documents for relevancy. Plaintiffs maintain that Lilly need not conduct a voluntary, time-consuming, and unnecessary relevance review of its production, as the parties' agreed-upon search terms are narrowly tailored such that all documents identified by the search terms are likely to be relevant, and moreover, all documents produced are subject to a protective order entered in this case. Lilly has insisted, however, that its relevance review was non-negotiable. Regardless, because Lilly has not provided any data to allow Plaintiffs to assess its undue burden claim, and Lilly's production of sales representatives' custodial files in the related Cymbalta cases have not shown that reviewing the documents identified by the parties' agreed-upon search terms would constitute undue burden, Lilly has not fulfilled its obligations to show that the requested discovery exceeds the scope of discovery permitted by the Federal Rules of Civil Procedure.

3. Courts routinely order production of sales representative custodial files.

Courts routinely order production of pharmaceutical sales representatives' custodial files. *See, e.g., Cunningham v. Smithkline Beecham*, 255 F.R.D. 474, 479 (granting request for "complete sales files"); *Baker v. Bayer Healthcare Pharm. Inc.*, No. 13-CV-00490, 2014 WL 5513854, at *2 (N.D. Cal. Oct. 31, 2014) (finding that sales call notes pertaining to plaintiff's doctors were relevant, as well as those from all sales representatives across the country, because "other sales call notes could also lead a jury to infer that [defendant's] campaign was so pervasive that any doctor, including Plaintiff's, would fail to heed any warning about the product"); and *In re Actos (Pioglitazone- Prods. Liab. Litig.)*, No. 6:11-MD-2299, 2013 WL 4776346, at *4 (W.D. La. Sept. 3, 2013) (in case involving Lilly, ordering production of thirty-seven sales-force custodial files, including those of fourteen district managers).

Here, Plaintiffs have only requested the custodial files of six of Lilly's sales representatives, out of thirty-five sales representatives identified in Lilly's sales call tracking spreadsheets, all subject to the parties' narrowly tailored, agreed-upon search terms. Because Lilly has not shown that its burden of

assembling and producing the custodial files exceeds the discovery allowed by the Federal Rules of Civil Procedure, Lilly should produce the custodial files of these six sales representatives.

B. The Imposition Of Date Restrictions Is Unnecessary And Improper Because They Cause Responsive And Highly Relevant Documents To Be Excluded.

1. The imposition of date restrictions has demonstrably excluded highly relevant documents.

In an effort to address Lilly's undue burden claims despite the lack of data in support thereof, Plaintiffs proposed date restrictions for each sales representative for whom they have requested files. Ex. D. Plaintiffs later further narrowed the date restrictions for their request as a good-faith compromise to address Lilly's continued claim of undue burden. Ex. F at 11-13. Subsequently, during Plaintiffs' counsel's review of Lilly's sales representatives' custodial files in a related Cymbalta case, Plaintiffs' counsel became aware that the imposition of date restrictions had caused responsive and highly relevant documents to be excluded. Ex. H. Many of the excluded documents relate directly to Lilly's communications with doctors regarding Cymbalta withdrawal, the core issue in this case.

As was demonstrated in related cases, the imposition of date restrictions in this case would likewise exclude responsive and relevant documents. To take one example, the imposition of date restrictions would likely cause responsive and highly relevant documents to be excluded from the custodial files of sales representative Kevin De Bruhl. Lilly's position is that Mr. De Bruhl's files should be limited to August 2004 to May 2006 because Cymbalta was not approved by the FDA until August 2004 and any documents prior to that date have no conceivable relevance. But Mr. De Bruhl's first visit with Dr. Smith was on August 25, 2004—twenty-one days after the FDA approved Cymbalta on August 4, 2004. It is unlikely that Lilly only provided Mr. De Bruhl with training materials about Cymbalta promotion during those twenty-one days; on the contrary, it is likely that Mr. De Bruhl received materials regarding Cymbalta promotion in the months leading up to the FDA's approval of Cymbalta. Any such materials would be highly relevant to Plaintiffs' claims, as Mr. De Bruhl was introducing Plaintiff's doctor to what was a brand-new drug, and how Lilly presented (or omitted) information about Cymbalta's benefit-risk profile would have been critical to doctors learning about the drug for the first time.

2. The imposition of date restrictions is unnecessary.

The imposition of date restrictions is not necessary because the parties' agreed-upon search terms inherently limit the universe of documents that Lilly would need to collect and review to those relevant to this litigation. Specifically, the parties' agreed-upon search terms require that the documents be responsive to both the "Cymbalta Terms" and the "Discontinuation Terms." Thus, any documents in the custodial files not responsive to the search terms would already be excluded from the collection and review process.

Again using Mr. De Bruhl's files as an example, if Lilly's claim that documents from any years before Cymbalta's approval in August 2004 have no conceivable relevance to this case is true, then when Lilly runs its search terms (including "Cymbalta" and "Discontinuation Terms"), no documents from these years would be "found" and become part of Lilly's relevance review.

3. Lilly's sole reason for insisting on the date restriction is unavailing.

Lilly insists that the date limitations are "reasonable and appropriate" because "it's what [Plaintiffs] first proposed[.]" Ex. F at 1. But at the time Plaintiffs proposed the date restrictions as a good-faith offer of compromise, Lilly had not run the search terms or date restrictions across any sales representatives' files to determine whether they would exclude responsive and relevant documents. Furthermore, Lilly refused to permit Plaintiffs to sample any sales representatives' files to ensure that relevant documents wouldn't be excluded. Plaintiffs' counsel became aware of the issue only after Lilly produced sales representatives' custodial files in related Cymbalta cases.

V. CONCLUSION

Plaintiffs respectfully ask the Court to compel Lilly to conduct electronic searches and produce the resulting discoverable documents pertaining to the custodial files of William Booth, Gay Bolenbaugh, Kevin De Bruhl, John Burke, Tracy Gaskins, and James Kiger, using the parties' agreed-upon search terms and without the imposition of unnecessary and improper date restrictions.

DATED: March 18, 2016

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CERTIFICATE OF SERVICE

I certify that on March 18, 2016, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the persons listed below:

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